IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Palmaz, et al.	Attorney Docket No.:	6006-015
Serial No.:	09/707,685	Examiner:	Cheryl L. Miller
Filed:	November 7, 2000	Art Unit:	3738
		Confirmation No.:	9696

Title: ENDOLUMINAL STENT, SELF-SUPPORTING ENDOLUMINAL GRAFT AND METHODS OF MAKING SAME

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I hereby certify that this document (along with any being referred to as enclosed and/or attached) are being filed electronically on this the 20th day of August, 2007, addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APPELLANTS' REPLY BRIEF ON APPEAL

Dear Sir:

Appellants submit this Appellants' Reply Brief on Appeal in response to the Examiner's Answer mailed 20 June 2007 for the above-identified application. Appellants do not believe any additional fees are due in connection with the filing of this Reply Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

APPELLANTS' REPLY BRIEF ON APPEAL

1. Status of Claims

Claims 1-38 and 54-66 have been cancelled. Claims 39-53 and 67-74 are pending and stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0018381 to Whitcher et al. In the Examiner's Answer dated 20 June 2007, the Examiner withdrew the rejection of claims 39-53 and 67-74 under 35 U.S.C. § 112, first paragraph. Appellants thank the Examiner for withdrawing the rejection under 35 U.S.C. § 112, first paragraph. The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) is under appeal.

2. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-53 and 67-74 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0018381 to Whitcher et al. (since issued as U.S. Patent No. 6,938,668).

3. Argument

The Examiner's rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as being anticipated by Whitcher et al. is improper and should be withdrawn.

Independent claims 39, 47, and 67, and the claims which depend therefrom, recite in relevant part, a method of manufacturing an endoluminal stent "under vacuum deposition process conditions selected to minimize (or substantially eliminate) formation of intra- and inter-granular precipitates in the bulk material." The Examiner asserts that Whitcher et al. discloses a method of manufacturing an endoluminal stent under process conditions selected "to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film." Applicants respectfully submit that the Examiners' assertion is unfounded. Minimizing precipitate formation is never mentioned in Whitcher et al. In fact, the term "precipitate" never appears in the disclosure of Whitcher et al.

For a prior art reference to anticipate a claim, the prior art reference must teach each and every element of the claim. *See* MPEP § 2131; *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (holding that "[t]he *identical* invention must be shown in as complete detail as is contained in the ... claim." [Emphasis added].); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation cannot be established by mere equivalents). The Examiner has failed to establish that Whitcher et al. anticipates the claims on appeal because Whitcher et al. does not teach, expressly or inherently, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film. Applicants submit that independent claims 39, 47, and 67, and the claims which depend therefrom, are patentable over the prior art cited and of record.

The claimed invention is generally directed toward a method for manufacturing an endoluminal stent comprising, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film.

The Examiner argues that the disclosure of minimizing precipitates in Whitcher et al. is inherent. The Examiner states:

> "Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc. P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such process control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as the applicants are."
>
> "Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a material's microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled."
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> Examiner's Answer, 20 June 2007, page 5.

Applicants submit that is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art. The Examiner has failed to provide any disclosure in Whitcher et al. that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Moreover, Applicants respectfully assert that the Examiner's reading of Whitcher et al. is incorrect. In contrast to the claims on appeal, Whitcher et al. broadly defines "vapor deposition" as any process of depositing metals and metal compounds by dissipating metal ions from a vaporous medium. Specifically disclosed are physical vapor deposition processes of evaporation and sputtering. Additionally, direct and assisted ion beam deposition and chemical vapor deposition are suggested as being useful. Whitcher et al., however, offers no guidance or teaching that any of these processes may be employed to form an as-deposited crystalline film by vacuum deposition while controlling the deposition process to minimize precipitate formation. Whitcher et al., merely states conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, none

of the Examples found in Whitcher et al. contain any statement or suggestion that the vacuum deposited film is crystalline, or that precipitate formation is, in fact, controlled.

The Examiner argues in the Final Office Action, the Advisory Action, and the Examiner's Answer that "Whitcher et al. discloses controlling the microcrystal structure" citing Paragraphs 0011, 0028, 0038, 0042 and 0043 of Whitcher et al. Based on these paragraphs of Whitcher et al., the Examiner argues that "inherently granular precipitates are controlled, since granular precipitates are an element of a materials microstructure." A review of the paragraphs cited by the Examiner, however, reveals that the cited paragraphs fail to support the Examiners' conclusions.

In Paragraph 0011, Whitcher et al. states, in relevant part, that "[t]he medical devices also have a crystallographic structure that is produced by the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, nanocrystalline and monocrystalline structures." First, the disclosure does not make sense and is internally inconsistent, as an amorphous structure is, by definition, not crystalline. Additionally, this paragraph merely provides a statement that the Whitcher et al. device may have either a nanocrystalline or monocrystalline structure.

Paragraph 0028 of Whitcher et al. states, in relevant part, that "[b]y using vapor deposition techniques for the formation of medical devices, the composition, thickness, surface roughness, and microstructure of devices formed in accordance with the present invention are accurately and precisely controlled." This paragraph provides a statement of objectives and does not expressly or inherently teach what aspects of the microstructure may be controlled, and thus fails to specifically teach that precipitates may be controlled.

Paragraph 0038 of Whitcher et al. states, in relevant part, that "[t]he removal of impurities and the filtering of particular isotopes are useful in the present invention. The crystalline structure of the metallic medical article may be affected by impurities. Single crystal or monocrystalline materials are more easily formed when levels of impurities are minimized." Again this paragraph is devoid of any teaching that the vacuum deposition process may be

controlled in such a manner as to minimize intra- and inter-granular precipitate formation and deposit a crystalline film. Monocrystalline (or single crystal) materials are taught by Whitcher et al. as drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure.

Additionally, the term "impurities," as mentioned in paragraph 0038 of Whitcher et al. and described in greater detail in paragraph 0037, actually refers to impurities, such as oxygen, in the "elemental ingot," not to actual precipitates, as the Examiner suggests. In fact, the process disclosed in Whitcher et al. exemplifies a conventional nitinol vacuum deposition process as known in the vacuum deposition art. In the conventional prior art nitinol vacuum deposition process, an elemental ingot material, *e.g.*, nitinol, is vacuum deposited as a thin metal film in an amorphous state onto a substrate. Paragraphs 0037 and 0038 and Figure 4B of Whitcher et al. teach filtering out impurities, such as oxygen, that are contained in the elemental ingot, before they are deposited onto a substrate. Because the deposited film is in an amorphous state, *i.e.*, non-crystalline state, an annealing step (synonymous to an aging process) is required to crystallize the thin film. Through an annealing process, precipitates inevitably form and are driven out of the solid solution. Paragraph 0064 of Whitcher et al. discloses a method for vacuum depositing a metal film wherein an annealing process is required. Accordingly, the method of forming a thin metal film through vacuum deposition disclosed in Whitcher et al. does not teach, expressly or inherently, minimizing precipitate formation because the method of Whitcher et al. requires an annealing step that would inevitably form precipitates.

In contrast to the conventional nitinol vacuum deposition process described in Whitcher et al., the claimed method eliminates the need for an annealing step. The claimed method achieves this by providing means for vacuum depositing a thin film that is in crystalline form as deposited. As a result, an annealing step is not required, and no precipitates are thereby formed. Thus, Applicants teach a method for minimizing precipitate formation that is distinguished from Whitcher et al. and is not taught by Whitcher et al.

Paragraph 0042 of Whitcher et al. provides that:

> "enhanced mechanical properties for medical devices can be obtained by minimizing grain size of the metallic structure. Conventional grain sizes are on the order of 10 microns or larger. A medical device with a nanocrystalline structure is useful because of its enhanced mechanical properties, for instance fatigue resistance and corrosion resistance. A nanocrystalline structure in a biocompatible material with a grain size ranging from about 1 to 500 nanometers is useful as a medical device. Also useful is a biocompatible material with a grain size of about 1 to 100 nanometers. Furthermore, a nanocrystalline structure in a biocompatible material with a grain size of about 1 to 50 nanometers is useful as a medical device. Moreover, a biocompatible material with a grain size of about 1 to 10 nanometers is also useful as a medical."

This teaching merely suggests that nano-scale crystal structures are desirable to enhance mechanical properties of the medical device. No teaching as to how the nanocrystalline structure is formed is found in this paragraph.

Paragraph 0043 of Whitcher et al., however, does offer the express teaching of how the nanocrystalline structure is formed, stating that:

> "Such nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques can be used to form nanometer sized crystals. [Referring to Paragraph 0041]. Furthermore, the orientation of the nanometer sized grains can be controlled to yield a orderly grain structure with substantially similar crystal orientation. A useful method for forming such structures is through epitaxy where desired material is deposited onto a substrate having a crystalline structure, such as an orientated, nanocrystalline structure, and the deposited material forms a crystalline structure similar to that of the substrate." [Emphasis added].

It is clear that Whitcher et al. teaches depositing a material onto a substrate **in its amorphous state**, and after deposition, treating or aging the amorphous structure (as expressly taught in Paragraph 0041) to form either a monocrystalline or nanocrystalline structure. This is, without

question, different and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation.

Analysis of the portions of Whitcher et al. to which the Examiner refers reveals that the Examiner's conclusions regarding Whitcher et al. are not supported by the disclosure of Whitcher et al. The Examiner argues: 1) that "granular precipitates are an element of a materials microstructure," 2) that "inherently the precipitates are controlled, because Whitcher et al. discloses selection of a process condition," 3) that the "amount and size of granular precipitates is dependent upon temp, pressure and rate," and 4) that "Whitcher et al. also clearly discloses filtering the metal during deposition to control the microstructure, thus inherently granular precipitates would be controlled, minimized, as they are part of the microstructure that would be filtered." The Examiner, however, fails to cite any portion of Whitcher et al. or any other prior art reference to support her assertions. It is well settled that an unsupported assertion or conclusion by an Examiner is insufficient basis for rejecting a claim.

Contrary to the Examiner's assertions, Whitcher et al. does not disclose, explicitly or inherently, that vacuum deposition may be controlled to minimize formation of precipitates in the as-deposited crystalline film. In fact, the word "precipitate" does not even appear in the disclosure of Whitcher et al. Applicants submit that the concept of controlling aspects of the microstructure of a deposited metal is different from the concept of minimizing precipitates in a deposited metal film. As widely known to those skilled in the metallurgical arts, the term "precipitate"[1] is different from the term "microstructure"[2] and different from the term "impurity"[3]. In the metallurgical arts as they pertain to fabrication of biomaterials, and with particular reference to nickel-titanium shape memory alloys, precipitates are reaction products

[1] Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

[2] Online website <www.dictionary.com> defines the term microstructure as "the structure of a metal or alloy as observed, after etching and polishing, under a high degree of magnification."

[3] Online website <www.dictionary.com> defines the term impurity as "the quality or state of being impure."

formed from a solid solution under increased thermal conditions which drive the precipitate from the solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, the metal crystalline structure.

Thus, a "precipitate" is not an "impurity." Rather, it is a reaction product from the solid metal solution. Conversely, an "impurity" is not a "precipitate." Indeed, in paragraph 0037, Whitcher et al. clearly notes that "other impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away from the substrate with this method." [Emphasis added]. There is no disclosure in Whitcher et al. indicating that the "impurities" described in Whitcher et al., and noted by the Examiner, actually refer to precipitates.

In fact, based on the description of Whitcher et al., the impurities described in Whitcher et al. cannot be precipitates. As previously discussed, in a conventional prior art nitinol vacuum deposition process, such as that of Whitcher et al., an elemental ingot material, *e.g.*, nitinol, is vacuum deposited as a thin metal film in an amorphous state onto a substrate. In such a conventional prior art nitinol vacuum deposition process, an annealing process is necessary to form precipitates and to drive these precipitates out of the solid solution. The precipitates themselves are not formed until commencement of the annealing process, which occurs after the filtering step described in Whitcher et al. Paragraphs 0037 and 0038 and Figure 4B of Whitcher et al. teach filtering out impurities, such as oxygen, that are contained in elemental ingot, before they are deposited onto a substrate. Because the filtering step of Whitcher et al. occurs before the annealing process, *i.e.*, before actual precipitate formation, the Examiner's interpretation of the passage "impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away..." in Paragraph 0037 of Whitcher et al. to encompass a teaching of filtering out precipitates is diametrically opposed to the actual teachings of Whitcher et al.

Furthermore, even assuming *arguendo* that the teaching in Whitcher et al. of controlling microstructure of the deposited metal were in some manner analogous to Applicants' teaching of minimizing precipitate formation of a deposited metal -- a position that Applicants strongly oppose, the Examiner's anticipation rejection would still be improper because Whitcher et al. does not qualify as an enabling prior art reference with regard to Applicants' pending claims.

Courts have consistently held that, for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel*, Inc. 314 F.3d 1313, 1354 (Fed. Cir. 2003) (stating that "a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled ... a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to 'enable one of skill in the art to reduce the disclosed invention to practice' " and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." [Emphasis added]. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. And Research*. 345 F.3d 1051, 1054 (Fed. Cir. 2003). In other words, in order "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." [Emphasis added]. *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

Whitcher et al. does not disclose precipitates or precipitate formation, let alone enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize formation of precipitates, as recited in independent claims 39, 47, and 67. Simply put, Applicants submit that the brief mention of controlling the microstructure of a vacuum deposited metal in Whitcher et al. does not enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize precipitate formation.

For at least these reasons, Applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

Conclusion

An anticipation rejection under 35 U.S.C. § 102(e) requires that the cited prior art reference must disclose each and every claimed element. Whitcher et al. does not teach or suggest every limitation recited in the pending claims on appeal. More specifically, Whitcher et al. fails to teach a method of manufacturing an endoluminal stent comprising the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film. Furthermore, Whitcher et al. does not enable the teachings for which the Examiner relies on Whitcher et al. Thus, Whitcher et al. does not anticipate the pending claims on appeal, and the Examiner's anticipation rejection is improper and should be withdrawn.

Accordingly, Applicants submit that pending claims 39-53 and 67-74 are patentable over the art cited and of record.

Respectfully submitted,

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